IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	**Case #: 3:05-00444**
	)	**Judge Trauger**
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF POST-INCIDENT REGULATORY ACTIONS, LABELING, AND PATIENT INFORMATION GUIDES

Plaintiff Ruth Smith, by and through her attorneys, respectfully requests that this Court deny in its entirety Defendants' motion *in limine* to exclude evidence of post-incident regulatory actions, labeling, and patient information guides because such information is relevant to various salient issues in this litigation, including failure to provide an adequate warning, the feasibility of a warning for off-label indications, and general causation under Fed. R. Evid. 401. Moreover, pursuant to Fed. R. Evid. 403, the probative value of such actions by the Food and Drug Administration regarding labeling changes provides information that is critical to Plaintiff's case in chief. Plaintiff would be severely prejudiced if same is not presented to a jury, and the admission of such evidence outweighs alleged unfair prejudice, if any, to Defendants. Additionally, Fed. R. Evid. 407 regarding subsequent remedial measures is inapplicable here because Defendants' actions in changing the label for their drug Neurontin, to warn of the risks

for mood and behavioral changes and an increased risk for suicide, etc., were not voluntary measures; in fact, Defendants clawed tooth and nail against making such changes, but were mandated to do so by the U.S. Food and Drug Administration. This Court is also advised that by an Electronic Order on July 24, 2009, Judge Patti B. Saris, the presiding judge of the Neurontin multidistrict litigation in the District of Massachusetts, has denied an essentially identical motion *in limine* (*see* D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1869), filed by Defendants in *Bulger v. Pfizer Inc.*, D. Mass. No. 1:07-cv-11426-PBS.

INTRODUCTION

On December 16, 2008, the FDA advised Defendant Pfizer Inc. that "based on new safety information regarding the risk of suicidal thoughts or behaviors with AEDs, a Risk Evaluation and Mitigation Strategy (RES) (including a Medication Guide) is required for Neurontin." *See* Declaration of Kenneth B. Fromson, Exhibit A. On March 17, 2009, the FDA informed Pfizer that the "Medication Guide should be comprehensive and should include all risk information reflective of your labeling that is necessary for patient's safe and effective use of Neurontin." *Id.* Consequently, the FDA-mandated 2009 Neurontin label and patient information guide contains some of the warnings that Plaintiff has advocated, and which Defendants should have provided, for their drug Neurontin prior to Plaintiff's decedent's suicide.[1] The pertinent information from the new 2009 Neurontin Label is as follows:

> **WARNINGS**
> **Suicidal Behavior and Ideation**

[1] Although Defendants' Memorandum cites to caselaw insinuating that Defendants could not have known of the risks (Docket No. 102 at 2), Judge Saris has recognized that Plaintiffs sufficiently countered that misplaced argument in their opposition briefing, D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1197, to Defendants' *Daubert* and summary judgment briefing. *See In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 153-57 (D. Mass. 2009). Judge Saris specifically stated: "In fact, when hired by Warner-Lambert to investigate the relationship between gabapentin and behavioral disturbances in the mid-1990s, Dr. Trimble (now one of Plaintiffs' experts) advised the company that one of the strongest associations with anticonvulsant drugs generally was to depression. (Trimble Rep. 29; *see* Michael Trimble, Psychosis with Gabapentin (Neurontin), May 20, 1995), Pls.' Ex. 17.))" *Id. at* 129.

> Antiepileptic drugs (AEDs), including Neurontin, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Fromson Decl., Ex. B.

It is clear from Judge Saris' May 5, 2009 decision denying Defendants' *Daubert* motion on general causation, that although the FDA analyses and subsequent actions alone were not determinative, the FDA's actions were central to the issue of general causation:

> Recognizing that the FDA meta-analysis, Alert, and subsequent actions were central to issues within the present motion, this Court requested FDA participation in the hearing in this matter.

612 F. Supp. 2d at 134 n.27. Further, Plaintiffs argued that the FDA study was strong evidence on general causation, and was a factor to be considered:

> Plaintiffs argue persuasively that even if this Court does not consider the FDA study as definitive proof of general causation, the study nevertheless qualifies as powerful epidemiological evidence establishing an association between Neurontin and suicidality.

Id. at 137. Judge Saris agreed, and made it perfectly clear that the FDA meta-analysis was to be considered in a determination on general causation:

> Moreover, the Reference Guide on Epidemiology suggests that a meta-analysis can itself be deemed an epidemiological study. *See* Reference Guide on Epidemiology, supra, at 380. For reasons discussed below, the Court finds that the FDA study is an epidemiological study that may be considered on the question of whether the Plaintiffs have produced evidence of an association between Neurontin and suicidality (the starting point for a causal inquiry under Bradford Hill).[2]

Id. at 137.

Defendants' arguments that the FDA post-incident regulatory actions, labeling and patient information guides are not relevant to the issue of general causation are disingenuous at

[2] Judge Saris went on to state it "considers the FDA study to be reliable and potent evidence supporting an association between Neurontin and depression or suicidality." *Id.* at 140.

best. The FDA actions, and change in Neurontin labeling and patient information guide affirm the general causation testimony of Plaintiff's experts, Dr. Trimble's warning, *id.* at 129, and the warning contained in the clinical review. *Id.* at 154. The regulatory actions show that Defendants could have performed adequate pre- and post-marketing pharmacovigilance in order to warn that the ingestion of Neurontin increased the risk for suicidality in off-label indications. Moreover, Plaintiff's decedent's prescribing physician, Dr. Edward Mackey, testified that had he been told that Neurontin was a drug that had problems with suicidality, he "probably" would have changed the way he treated Richard Smith (*see* Mackey Dep. 42:17-25, D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679, Ex. 12); and that had he known of these problems associated with Neurontin, he "[c]ertainly" "would have . . . at least put out some warnings and some safeties and precautions and told them what to be observant about." *Id.* at 43:1-9. Defendants' actions, in suppressing and fraudulently concealing that the ingestion of Neurontin causes adverse mood and behavior changes and increases the risk for suicidality, resulted in preventing Mr. Smith and his prescribing physician(s) from being able to fully assess the risk-benefit analysis for the underlying off-label condition for which Neurontin was prescribed to Mr. Smith, and from being able to fully monitor changes in Mr. Smith's mood and behavior caused by Neurontin. Defendants could have — and should have — performed adequate studies and pharmacovigilance and provided a similar warning on the Neurontin label and patient information guides, etc., that was mandated by the FDA on the new 2009 Neurontin label for "any indication" (including off-label uses) after the FDA's meta-analyses. Consequently, the 2009 Neurontin label is required by Plaintiff to show that such labeling was feasible.

ARGUMENT

The 2009 label and patient information guides, etc., is not a "subsequent remedial measure" because it was the product of FDA meta-analyses of the risks associated with antiepileptic drugs and regulation, rather than a voluntary decision by Defendants to make their product safer. But even if the label were a subsequent remedial measure, Plaintiff does not offer the label to prove Defendants' culpability. Rather, Plaintiff offers the label as part of the evidence concerning general causation, feasibility of such a warning for off-label indications, among other admissible purposes. The probative value of this evidence on issues such as general causation, failure to warn etc., far outweighs any potential for unfair prejudice to Defendants.

POINT I

THE NEW 2009 LABEL AND PRODUCT INFORMATION, ETC., ARE NOT SUBSEQUENT REMEDIAL MEASURES BECAUSE THEY ARE NOT THE PRODUCT OF THIRD-PARTY INITIATIVE, NOT DEFENDANTS' SAFETY CONSCIOUSNESS

The principal purpose of Fed. R. Evid. 407 is to establish "a social policy of encouraging people to take, or at least not discouraging them from taking, steps in furtherance of added safety"[3] Consequently, Rule 407 applies solely to safety measures undertaken by Defendants and not those brought about by an entity other than a party to the suit.[4]

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[3] Fed. R. Evid. 407 Advisory Committee Notes; *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 415 (3d Cir. 2002); *DeLuryea v. Winthrop Labs.*, 697 F.2d 222, 228 (8th Cir. 1983).

[4] *See., e.g. Diehg v. Blaw-Knox*, 360 F.3d 426, 430 (3d Cir. 2004) ("This policy is not implicated where the evidence concerns remedial measures taken by an individual or entity that is not a party to the lawsuit. The admission of remedial measures by a non-party necessarily will not expose that non-party to liability, and therefore will not discourage the non-party from taking the remedial measures in the first place."); *Mehojah v. Drummond*, 56 F.3d 1213, 1215 (10th Cir.1995); *TLT-Babcock, Inc. v. Emerson Elec. Co.*, 33 F.3d 397, 400 (4th Cir.1994); *Raymond v. Raymond Corp.*, 938 F.2d 1518, 1523-24 (1st Cir.1991) (First Circuit. noted that Rule 407 "applies only to subsequent remedial measures taken voluntarily *by the defendant")*; *Pau v. Yosemite Park & Curry Co.*, 928 F.2d 880, 888 (9th Cir.1991); *O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1204 (8th Cir.1990); *Dixon v. Int'l Harvester Co.*, 754 F.2d 573, 583 (5th Cir.1985); *Lolie v. Ohio Brass Co.*, 502 F.2d 741, 744 (7th Cir.1974) (per curiam). *See generally* 2 Weinstein's Federal Evidence § 407.05[2] (Joseph M. McLaughlin ed., 2d ed. 2003).

The rationale for exclusion disappears when the "subsequent remedial measure" was not undertaken voluntarily, but was required by a regulatory body. *See Rozier v. Ford Motor Co.*, 573 F.2d 1332, 1343 (5th Cir. 1978) ("Invoking this policy to justify exclusion here is particularly inappropriate since the estimate was prepared not out of a sense of social responsibility but because the remedial measure was to be required in any event by a superior authority, the National Highway Traffic Safety Administration."); *Espeaignnette v. Gene Tierney* Co., 43 F.3d 1, 10 (1st Cir. 1994) (noting that "circuit precedent clearly establishes that Rule 407 does not apply to actions taken by third parties"). "Where a superior authority requires a tortfeasor to make postaccident repairs, the policy of encouraging voluntary repairs which underlies Rule 407 has no force — a tortfeasor cannot be discouraged from voluntarily making repairs if he must make repairs in any case." *Hearndon v. Seven Bar Flying Serv., Inc.*, 716 F.2d 1322, 1331 (10th Cir.1983), *cert. denied, sub nom, Piper Aircraft Corp. v. Seven Bar Flying Serv. Inc.*, 466 U.S. 958 (1984).

In *Lolie v. Ohio Brass Co.*, 502 F.2d 741, 744 (7th Cir. 1974), the plaintiff's husband was killed when he was struck by a power cable that fell in a coal mine. The district court excluded evidence that after the incident, a state mine inspector directed that the cable be given additional support. The Court of Appeals held that the trial judge had wrongfully excluded the evidence because "there existed no valid policy reason for excluding it:" the defendant-clip manufacturer had not taken the additional safety precautions voluntarily, but because the inspector had required it to do so. *Id.*

In *Kociemba v. G.D. Searle & Co.* 683 F. Supp. 1579, 1581 (D. Minn. 1988), the district court said that a post-event warning, issued at the behest of the FDA, rather than initiated by the manufacturer of the drug is not a "subsequent remedial measure" within the meaning of Fed. R.

Evid. 407. Kociemba alleged that she was injured from using an IUD. A month before she obtained the IUD, the FDA enacted a regulation requiring additional warnings. The regulation did not become effective until four months after she obtained the IUD, however, and the manufacturer filed a motion in limine, arguing that Rule 407 excluded any evidence of the changed warning as a subsequent remedial measure. The district court denied the motion *in limine*, holding, *inter alia*, that "where a superior authority requires a tortfeasor to make post-accident repairs, the policy of encouraging voluntary repairs which underlies Rule 407 has no force — a tortfeasor can not be discouraged from voluntarily making repairs if he must make repairs in any case." 683 F. Supp. at 1581 (quoting *Hearndon*). This is of course essentially the same situation the Court faces in the case at bar.

The 2009 label and product information, etc., for Neurontin were the result of analysis and actions taken by the FDA rather than an any undertakings pursued by Defendants. The FDA's meta-analysis and decisions of the FDA panel gave rise to the label. In fact, Defendants resisted tooth and nail the FDA determinations concerning the study and the FDA Advisory Panel, whose July 2008 vote and recommendation ultimately gave rise to the amended label which provides warnings concerning that Neurontin increases the risk for suicide for off-label indications. Once the FDA meta-analysis revealed the increased risk for suicide caused by Neurontin, Defendants were obliged by law to change the product label. Fromson Decl., Ex. A. Indeed, Defendants, like all drug manufacturers, are required to notify the FDA immediately when new studies reveal greater risks than previously disclosed.[5] And Defendants must submit a change in labeling whenever new incidents of adverse events are reported, so long as there is a substantial association with Defendants' product (even if causation is not established). Hence, the 2009 Neurontin label was a product of the FDA analyses and thrust upon Defendants. It was

[5] 21 C.F.R. § 314.80.

not a label Defendants adopted on their own volition, in furtherance of public safety. Rule 407's policy of encouraging companies to make their products safer would not be impacted by admission of evidence of the 2009 Neurontin label and product information guide, etc.

Defendants claim that "feasibility is not disputed here." Docket No. 102 at 6. However, Defendants have asserted that Richard Smith's physicians prescribed Neurontin off-label and had no duty to warn. Yet, the new 2009 Neurontin label demonstrates the feasibility of including such a warning for off-label uses.

POINT II

INDEPENDENTLY, THE 2009 LABEL IS BEING OFFERED FOR A NUMBER OF ADMISSIBLE PURPOSES, NONE OF WHICH INVOLVE PROVING CULPABILITY

Contrary to Defendants' claim, Fed. R. Evid. 407 is not a global prohibition on evidence of subsequent remedial measures; rather, it is a narrow exception to admissibility that forbids such evidence only when introduced to prove wrongful conduct. Rule 407 states:

> When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction. **This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose**, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment. [Emphasis added.]

By the express terms of the rule, the enumerated exceptions are nothing more than examples of permissible uses of such evidence. So long as the evidence is not introduced to prove the defendant's culpability, it should be allowed.

A. Evidence of the 2009 Label Is Essential to Prove Causation — That an Adequate Warning Would Likely Have Averted the Injury

As noted in detail above, Judge Saris has stated that the "FDA meta-analysis, Alert, and subsequent actions were central" to the issue of general causation. 612 F. Supp. 2d at 134 n.27.

Moreover, Judge Saris considered that the "FDA study is an epidemiological study that may be considered on the question of whether the Plaintiffs have produced evidence of an association between Neurontin and suicidality (the starting point for a causal inquiry under Bradford Hill" *Id.* at 137. Defendants' actions, in suppressing and fraudulently concealing that the ingestion of Neurontin causes adverse mood and behavior changes and increases the risk for suicidality, resulted in preventing Richard Smith and his prescribing physician(s) from being able to fully assess the risk-benefit analysis for the underlying off-label condition for which Neurontin was prescribed to Mr. Smith, and from being able to fully monitor changes in Mr. Smith's mood and behavior caused by Neurontin. It almost goes without saying that a prerequisite to recovery on a failure to warn claim is proof that an adequate warning would likely have averted the injury. And to prove such a claim, a plaintiff must, at a minimum, identify the contents of the warning that he contends should have been issued.

Plaintiff's experts have identified several warnings regarding suicide and adverse changes in mood and behavior which should have been included in the label for Neurontin. Fromson Decl., Ex. B. Plaintiff cannot meet her burden of proving causation if she is not allowed to introduce evidence of the very warnings that would have averted Mr. Smith's injury. Again, the evidence is being offered to prove causation, not culpability.

But there is an even more telling reason the evidence is essential to causation. One of Plaintiff's principal claims is that Defendants were obligated to perform adequate pharmacovigilance for off-label uses of their drug. Had Defendants done so, they would have been obligated under the law to include on the Neurontin label and patient information guide, etc., some of the warnings that Plaintiff's experts have advocated, including that ingestion of Neurontin causes an increased risk for suicide, and that physicians should monitor for adverse

changes in mood and behavior. These are essentially the same warnings which appear on the new 2009 Neurontin label for all indications, including off-label uses. Plaintiff's experts will testify in this regard at trial. Of course, the basis for their conclusion is reality — when the FDA meta-analysis of 11 antiepileptic drugs was conducted, it yielded the results that dictate the change in the new 2009 label and patient guide for Neurontin. But if Plaintiff is not allowed to discuss the new 2009 Neurontin label, etc., the experts' testimony will occur in a vacuum. They will not be able to explain the basis for their conclusion that adequate pre-marketing and post-marketing pharmacovigilance would have produced such warnings, and their testimony will lack credibility. Evidence of the new 2009 Neurontin label and patient information guide, etc., is essential for Plaintiff to prevail on the failure to perform adequate pharmacovigilance element of both his negligence and failure to warn claims.

B. Evidence of the 2009 Neurontin Label and Patient Information Guide Demonstrates That the FDA Agrees That There Are Many Different Events Related to Suicidality

Plaintiff's experts have argued that Defendants should have been considering a constellation of psychiatric adverse events when monitoring the safety of the Neurontin with respect to suicidality. In the patient guide mandated by the FDA, several symptoms are described as relevant to suicidality:

> **2. Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:**
>
> • thoughts about suicide or dying
> • attempts to commit suicide
> • new or worse depression
> • new or worse anxiety
> • feeling agitated or restless
> • panic attacks
> • trouble sleeping (insomnia)
> • new or worse irritability
> • acting aggressive, being angry, or violent

- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

Fromson Decl., Ex. A at 8.

In her expert report, Dr. Cheryl Blume looked to these very same adverse conditions as part of her review of the evidence. Consistently, Defendants criticized Dr. Blume for having done so.[6] The FDA's actions definitively establish that Dr. Blume was correct in her review and that Defendants' criticisms are without merit.

C. Evidence of the 2009 Neurontin Label and Patient Information Guide Is Essential to Prove The Feasibility of Implementing Such Warnings Earlier

Under the express terms of Fed. R. Evid. 407, as noted *supra*, evidence of subsequent remedial measures is admissible to prove the feasibility of precautionary measures. *See also Estate of Spinosa,* 621 F.2d 1154, 1160 (1st Cir. 1980) ("evidence is admissible when used to rebut testimony asserting that particular designs are not feasible"). Contrary to Defendants' assertions otherwise, it is clear from their Memorandum that they claim the 2009 label was infeasible in the sense that the information upon which it was based was not available earlier. Defs. Mem., Docket No. 102 at 6. Furthermore, Defendants have consistently argued the opposite, that even though Defendants illegally marketed Neurontin for off-label uses, they were not obligated to warn for off-label uses because the physicians decided such uses — the FDA-mandated new 2009 label demonstrates the feasibility of providing a warning for "any indication" which includes off-label uses that were not approved by the FDA.

Defendants' argument ignores that Plaintiff is not suggesting that Defendants should have enacted the label in a vacuum. Rather, Plaintiff contends only that Defendants should have conducted adequate clinical studies for the off-label uses and adequate pre-marketing and post-

[6] *See generally* reports of Janet Arrowsmith-Lowe, Alex Ruggieri and Sheila Weiss Smith.

marketing pharmacovigilance. The results of such pharmacovigilance for off-label uses would have led to the labeling changes that ultimately became the 2009 Neurontin label. Plaintiff should be allowed to introduce evidence that adequate pre-marketing and post-marketing for off-label uses for which Defendants illegally marketed Neurontin would have yielded a label with equal or substantially similar warning for off-label uses as the 2009 Neurontin label and patient information guide. This evidence is offered to prove feasibility, not negligence.

POINT III

NEURONTIN'S NEW 2009 LABELING AND PATIENT INFORMATION GUIDES ARE NOT ONLY RELEVANT, BUT CRITICAL TO SALIENT ISSUES IN PLAINTIFF'S CASE AND WILL NOT CAUSE UNFAIR PREJUDICE TO DEFENDANTS

As noted in detail above, the new Neurontin 2009 labeling and patient information guides are relevant and critical to the issues of general causation, and the feasibility of providing some of the warnings that Plaintiff's experts on general causation have advocated in this litigation. Moreover, the new guides indicate that there were studies and pharmacovigilance that Defendants could have performed to issue the appropriate warnings. Defendants had a duty under the federal regulations to assess a warning of increased suicidality associated with the ingestion of Neurontin prior to Richard Smith's ingestion of same. 21 C.F.R § 314.70;[7] 21 C.F.R. § 201.80(e). When the FDA clinical review (1992) warned of the increased risk for suicidality, *supra*, and Dr. Trimble warned of depression and anti-epileptics (1995), *supra*, Defendants should have performed the required studies, pharmacovigilance and voluntarily added the appropriate warning. Because Defendants failed to issue an adequate warning, the FDA performed a meta-analyses and made a determination and the FDA required the new 2009

[7] Note that 21 C.F.R. § 314.70 was amended on April 8, 2004. Prior to that time — and at all times relevant to the issues in this lawsuit — a drug manufacturer could give an additional warning without notifying the FDA beforehand, but had to file a supplement with the FDA "at the time the applicant makes any kind of change." The current version of this section provides that the manufacturer must file its supplement 30 days prior to distributing a drug containing any such change. 69 Fed. Reg. 18728-01, 18764 (2004).

Neurontin label change — the purpose of Rule 407 was no longer served, and this Court should not exclude the added warnings from evidence.

Furthermore, the new 2009 Neurontin label changes and patient information guide, etc., also demonstrate that it was feasible to warn of "any indication" including off-label uses and not solely for the indications which were previously approved by the FDA for Neurontin.

To be admissible, evidence must be relevant. Fed. R. Evid. 401. Relevant evidence is evidence which may tend to prove or disprove a material fact that is of consequence to the determination of the action. Fed. R. Evid. 401. Further, the Federal Rules of Evidence provide that "relevant evidence may be excluded if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury or (b) undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403 (emphasis added). As discussed at length above, the new Neurontin 2009 label and patient information guides are relevant and critical to Plaintiff's prosecution of this case on the issues of general causation, and the feasibility of the warnings for Neurontin for off-label uses. Judge Saris has recognized that the FDA Alert, the FDA hearing and determinations in regard to their meta-analysis etc., were critical to issues of causation in this case and analyzed same in depth in its decision to deny Defendants' *Daubert* motions in their entirety. *In re Neurontin*, 612 F. Supp. 2d 116. This Court is perfectly capable in ensuring that this evidence will not confuse or mislead the jury.

That Judge Saris found the FDA determinations important to this litigation demonstrates that the new 2009 Neurontin label is not a waste of judicial resources. The probative value of presenting the 2009 Neurontin label, etc., which is the ultimate determination of the FDA, substantially outweighs the risk of confusing, misleading or inflaming the jury, or wasting judicial resources, and this evidence is admissible and should not be excluded.

CONCLUSION

Plaintiff respectfully requests that this Court deny Defendants' motion *in limine* to exclude evidence of post-incident regulatory actions, labeling, and patient information guide as such actions, labeling etc., are extremely relevant to salient issues in the case including Defendants' breach of duty of care and general causation, and their probative value greatly outweighs any alleged prejudice to Defendants by the admission of these documents.

Dated: April 27, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 27th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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